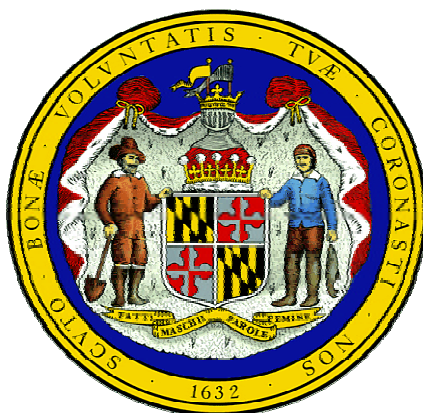


An Analysis and Evaluation of Certificate of Need Regulation in Maryland

**Working Paper: Specialized Health Care - Organ Transplant
Surgery, Neonatal Intensive Care Unit, and Burn Care Services**

*Analysis of Public Comments
and Staff Recommendation*



MARYLAND HEALTH CARE COMMISSION

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Summary and Analysis of Public Comments and Staff Recommendation

An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Organ Transplant Surgery, Neonatal Intensive Care Services, and Burn Services

I. Introduction

The Maryland Health Care Commission's working paper, titled *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Organ Transplant Surgery, Neonatal Intensive Care Services (NICU), and Burn Services*, was developed by Staff to the Maryland Health Care Commission (MHCC) as one in a series of working papers examining major policy issues of the Certificate of Need process, as required by House Bill 995 (1999). The paper provided background on the utilization of these three specialized services in Maryland. Additionally, the paper provided the following five options representing potential alternative regulation strategies for the Commission's consideration:

- Option 1: Maintain Existing Certificate of Need Program Regulation
- Option 2: Strengthen CON Regulation
- Option 3: Modify CON Oversight
- Option 4: Deregulate Organ Transplant Surgery, NICU, and Burn Services;
Create Data Reporting Model
- Option 5: Deregulate Organ Transplant Surgery, NICU, and Burn Services
from CON Review

The working paper was released for public comment at the Commission's October 18, 2001 meeting. A total of three organizations submitted written comments regarding the information and alternative regulatory options. These public comments are summarized in Part II and a Staff analysis of the public comments is provided in Part III. Part IV presents Staff's proposal for the Commission's recommendation to the General Assembly on whether to continue to regulate organ transplant surgery, NICU, and burn services in Maryland through Certificate of Need. Public comment on this document, and on Staff's proposed recommendation, is due to the Commission by close of business on **January 3, 2002**.

The organizations providing public comment include one hospital, one county Board of Health, and one hospital system. These entities are listed below:

- Holy Cross Hospital
- Howard County Board of Health
- MedStar Health

II. Summary of Public Comments¹

Holy Cross Hospital supports Option 1 (Maintain Existing Certificate of Need Program Regulation). The Hospital believes that there is a public interest in promoting quality, access, and cost containment in the health care system and maintains that the Certificate of Need process is an effective tool for implementing these measures. Additionally, **Holy Cross Hospital** believes that “consistency with the requirements of a specified authority in the field, as is now required for both NICU and hematopoietic stem cell transplant programs, is appropriate as part of the CON requirements.”

Likewise, the **MedStar Health**² supports Option 1 (Maintain Existing Certificate of Need Program Regulation). According to **MedStar Health**, a hospital’s success at providing specialized services such as organ transplant surgery, NICU, and burn services should be “subject to a carefully considered approval process and rigorous review procedures.” **MedStar Health** also provides the following reasons for continuing regulation regarding organ transplant surgery, NICU, and burn services:

- High volume programs tend to have better outcomes than lower volume providers of similar services. **MedStar Health** supports the continuation of existing CON regulations and policies, that concentrate volume in fewer centers through a managed growth strategy.
- Staff shortages are driving up hospital costs and Maryland hospitals are facing a severe shortage of health care workers. Specialized services are being affected the most because they require personnel with advanced training and knowledge who are scarce and more expensive to recruit and train. **MedStar Health** believes that Maryland’s CON process provides the oversight for reviewing the need of specialized programs such as organ transplant surgery, NICU, and burn services.
- The CON review process provides a mechanism for reviewing need and planning for organ transplant surgery, NICU, and burn services on a regional basis across jurisdictions.

MedStar Health also states that Options 2 (Strengthen CON Regulation) and 4 (Deregulate Organ Transplant Surgery, NICU, and Burn Services; Create Data Reporting Model) “propose to remove CON requirements, as they relate to either market entry or exit and quality for these specialized services, in favor of more intensive, ongoing scrutiny of these programs.” While **MedStar Health** believes there are benefits to using licensure to regulate some services, it does not believe that more intensive licensure or accreditation would be a

¹ A complete set of the written copies received on the Organ Transplant Surgery, Neonatal Intensive Care Services, and Burn Services Working Paper is attached and may also be obtained by contacting the Division of Health Resources at (410) 764-3232.

² The hospital affiliates of MedStar Health include, among others, Franklin Square Hospital Center, Good Samaritan Hospital, Harbor Hospital, and Union Memorial Hospital in Maryland and Georgetown University Hospital, National Rehabilitation Hospital, and Washington Hospital Center in the District of Columbia.

substitute for CON. **MedStar Health** also believes that Options 1 and 2 are not mutually exclusive since Option 2 actually complements Option 1.

Although **MedStar Health** states that it could support Options 3 (Modify CON Oversight) and 4 (Deregulate Organ Transplant Surgery, NICU, and Burn Services; Create Data Reporting Model) as quality-enhancing measures when maintaining the existing CON regulations, it does not consider them substitutes for the existing CON regulations.

Comments from the **Howard County Board of Health** support Option 1 (Maintain Existing Certificate of Need Program Regulation).

III. Staff Analysis of Public Comments

The clear consensus among the commenting providers is that CON regulation should continue. Staff concurs with the reasons that those commenting support continuing CON for these services: (1) services are finally and geographically accessible to all Maryland residents, (2) patients have access to the highest quality health care, (3) the development of organ transplant surgery, NICU, and burn services are consistent with Maryland policies, and (4) these specialized health care providers are accountable to the public.

Although none of the commenters supports these options in their entirety, **MedStar Health** notes that Option 2 harmonizes with the current CON regulation. **MedStar Health** believes that the ability to impose administrative sanctions could provide the Commission with a less rigid method to ensure compliance with certain imposed conditions. However, minimum volume standards, and other quality-related conditions, should not be subject to administrative sanctions that would allow inferior quality programs to remain in operation. Additionally, **MedStar Health** states that while Option 3 [Deregulate from CON and increase quality oversight by the Office of Health Care Quality (OHCQ)] and Option 4 (Deregulate from CON and create data reporting model) could enhance the quality measures in the existing CON regulation, it does not think these options are substitutes for the existing CON regulations. Staff believes it is reasonable that some of the recommended options would overlap and/or work concurrently with each other.

Option 5 received no support among the comments submitted to the Working Paper. This option would remove the requirement for Certificate of Need review and approval for the establishment or expansion of new organ transplant surgery programs, neonatal intensive care units, or burn treatment programs. Likewise it would remove any level of administrative review for the closure of an existing and operating program. Removing CON from these programs would neither affect whether programs seek voluntary accreditation or designation from a related State agency (i.e., the Kidney Commission, for kidney transplant programs) or an appropriate private authority [i.e., the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) for hematopoietic stem cell transplant programs], nor would it affect the authority of Health Services Cost Review Commission (HSCRC) to establish rates for neonatal intensive care and burn care. Staff believes that removing the CON requirement would not be advisable. If such an action were taken, no consistent oversight from other State or accreditation agencies would take the place of the threshold review for financial feasibility,

technical expertise, and sufficient volume that CON review provides since services are not separately licensed, and there would be no barriers to either market entry or market exit. The following table summarizes the options and how commenters responded to them:

Table 1
Options Supported in Public Comments

	Regulate		Deregulate		
	Option 1	Option 2	Option 3	Option 4	Option 5
Facility	Maintain Existing CON Regulation	Strengthen CON Regulation	Deregulate from CON, Increase Quality Oversight by OHCQ	Deregulate from CON, Create Data Reporting Model	Deregulate Specialized Services from CON Review
Holy Cross Hospital	X				
Howard County Board of Health	X				
MedStar Health	X				
Total:	3				

IV. Staff Recommendation

As shown in Table 1, **Holy Cross Hospital**, **Howard County Board of Health**, and **MedStar Health** support maintaining CON regulation of organ transplant surgery, NICU, and burn services. Likewise, the Commission received similar comments in connection with the option paper, *Organ Transplant Services; Regulatory Issues and Policy Options* that was released for public comment on September 13, 2001. Specifically, **Johns Hopkins Health System (JHHS)**, **MedStar**, and the **University of Maryland Medical Center (UMMC)** submitted written comments. No changes were suggested by the comments, and all three organizations supported Option 1, maintaining the current categories of covered transplant programs. Staff concurred with these commenters and, during the November 15, 2001 Commission meeting, recommended maintaining the current State Health Plan policy on categories of transplant programs covered by the CON program.

Maintaining the CON requirement for new programs in these specialized services helps to ensure the level of regionalization needed to promote higher volumes in each program. With regard to each of these services, a strong consensus exists that higher volumes translate into the type of experience required to develop the utmost level of skill and the greatest outcomes. At the same time, each program is reviewed against specific State Health Plan standards and is customized based upon the need for each service. Having reviewed and evaluated the entire structure of government oversight of organ transplant surgery, NICU, and burn services in Maryland, Staff concurs and recommends Option 1 (Maintain Existing Certificate of Need Program Regulation).

The consensus from commenting providers in favor of maintaining the current CON regulation, credits the existing Certificate of Need process with furnishing stability for organ transplant surgery, NICU, and burn services care in Maryland. Under Maryland law since 1988, Certificate of Need approval is required for the establishment of a new organ transplant service, NICU service, or burn care service. Since the imposition of this CON requirement, no hospital has applied to establish a second burn treatment center. Therefore, there is no State

Health Plan section that deals with burn services as there are for both organ transplant surgery and NICUs. As Staff pointed out in the Working Paper, organ transplant surgery, NICU, and burn services are all provided by hospitals. Consequently, the statute enacted in 1999 as part of HB 994 applies to any proposal to close these services.

Based on both the study and analysis performed during the preparation of its working paper *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Organ Transplant Surgery, Neonatal Intensive Care Services, and Burn Services*, and its consideration of the public comments received in response to the Working Paper, Staff recommends that the Commission continue to regulate the establishment of organ transplant surgery, NICU, and burn services by the means of the existing Certificate of Need process. Staff believes that the current Certificate of Need process is in the public interest because it promotes quality, access to care, and cost containment in the health care system in Maryland. Staff's recommendation to retain CON regulation of organ transplant surgery, NICU, and burn services would not preclude working with the Office of Health Care Quality to expand State licensure requirements regarding these specialized services to allow enhanced quality and access measures.

Attachment

Written Public Comments Received on the Working Paper entitled *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Organ Transplant Surgery, Neonatal Intensive Care Services, and Burn Services*